



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 September 2020

Submission of comments on 'CVMP strategy on antimicrobials 2021-2025' (EMA/CVMP/179874/2020)

Comments from:

Name of organisation or individual

Federation of Veterinarians of Europe (FVE)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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1. General comments

Stakeholder number <i>(To be completed by the Agency)</i>	General comment (if any)	Outcome (if applicable) <i>(To be completed by the Agency)</i>
	<p>FVE welcomes CVMP Strategy on antimicrobials 2021-2025.</p> <p>We very much welcome the CVMP mission statement, however suggest to include the environmental aspect. As recognised in the mission, it is very important to balance the risk to public health that could arise from the use of antimicrobials in animals, against the need to protect animal health and welfare.</p> <p>Our main feedbacks are:</p> <ul style="list-style-type: none"> - Animal welfare is missing in the entire Strategy - The Strategy defines an ambitious program. Prioritisation and a timeline might be worthwhile additions. - A reference to the Farm to Fork Strategy adopted in May and its goals in respect to antimicrobials should to be included. - We understand and agree that Regulation 2019/6 was used as reference for the definition of antimicrobials. However, resistance against antiparasitic products is also a growing problem and therefore we see a need for an additional strategy to cover aspects related to the use of antiparacsitics as well . 	

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	<ul style="list-style-type: none"> - We strongly support the need for the development of clinical breakpoints and values. - Lot of focus is being put on the risk assessment, but it would be preferable to consider more the risk mitigation measures e. g. in Aim 1 and Aim 2. More focus could also be put on the aspect of route of administration. - It would be good to detail the role that UPD can play in facilitating Aim 3 and Aim 5 e.g. to open up the possibility for more prudent and responsible use, by allowing, for example, the use of a lower category antibiotic from another EU country, or the use of alternatives to antibiotics. - There is an increasing trend to restrict antibiotics allowed to be used in animals, while several indications could be easily controlled via a narrow spectrum antibiotic available in another country or simply by increasing the dose of a currently available narrow spectrum antibiotic in the same country. Nevertheless, none of these scientifically acceptable options is currently allowed. In other cases, however, there are indications, where a shorter duration of treatment is proven to be as effective as the one indicated in the PIL. Pharmaceutical companies are hesitant to change the SPC and 	

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	<p>the used parameters to cover such issues, seen the amount of resources needed to do so. In addition, new treatment concepts (like the Mutant Prevention Concentration theory) are currently not allowed/available in practice. It would be great if the CVMP would really promote new opportunities for treatment with narrow spectrum antibiotics or lower dosage/duration – when possible and the use of other alternative options to facilitate responsible use of antibiotics in animals, rather than continuing to restrict the available options causing more problems in animal health and welfare.</p> <ul style="list-style-type: none"> - FVE welcomes that a reflection will be made upon the use of currently available tests and novel rapid diagnostic testing methods as a means to improve rational prescribing. Practical implications, such as how easy it is to take a sample, how many animals to sample, time it takes to get the results, costs of testing and animal owners willingness to pay for that, availability of tests in the different parts of Europe, should also be taken into account. <p>It is nice to see in the annex an overview of the activities undertaken by CVMP in 2016-2020</p>	

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	<p>(EMA/CVMP, 2016a). It is noted that some actions are still ongoing. It would be good to check at a certain moment the effectiveness, relevance, coherence and importance of the different actions taken, based on an assessment by the different regulatory authorities and stakeholders, in order to facilitate future prioritisation.</p>	

2. Specific comments on text

Line number(s) of the relevant text <i>(e.g. Lines 20-23)</i>	Stakeholder number <i>(To be completed by the Agency)</i>	Comment and rationale; proposed changes <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i>	Outcome <i>(To be completed by the Agency)</i>
Line 24-26		<p>Comment: In the introduction, the effect of AMR on human health is mentioned, but the effect on the health and welfare of animals is missing. Please add.</p> <p>Proposed change: Please add a sentence on the effect of AMR on animal health and welfare.</p>	
Line 45		<p>Comment: add the environmental aspect in the mission</p> <p>Proposed change: 'The CVMP's mission is to ensure the availability of effective antimicrobial medicines for the treatment of infectious diseases of animals while, at the same time, minimising the risks to animals, humans or the environment arising from their use.'</p>	
Line 58		<p>Comment: add animal welfare</p> <p>Proposed change: 'Aim 2: To consider and advise on the risk to public health that could arise from the use of antimicrobials in animals, and to balance this against the need to protect animal health and welfare'</p>	
Line 63		<p>Comment: add disease patterns.</p> <p>Proposed change: 'The AMEG's categorisation will be reviewed as required to take account of evolving patterns of AMR, antibiotic usage and disease patterns in human and</p>	

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		veterinary medicine.'	
Line 66		<p>Comment: Text mentions 'encouraging surveillance for changes in susceptibility of target pathogens and zoonotic bacteria,'. Will commensal bacteria also be included?</p> <p>Proposed change: /</p>	
Line 67		<p>Comment: remove the word 'especially'</p> <p>Proposed change (if any):. ... and subsequently, reviewing the authorisation of substances and/or products, <i>especially</i> when there is evidence that there may be a related change in the benefit-risk of the authorisation.</p>	
Line 70		<p>Comments: add animal categories</p> <p>Proposed change: 'CVMP will provide support to ESVAC in its preparations to receive data on sales and use of antimicrobials by animal species <i>and animal categories</i>, ...'</p>	
Line 81		<p>Comment: For several species, indications, the cascade is the only option available to treat an animal with an antibiotic. Restrictions should only be put on <u>certain antibiotic classes</u> or <u>for certain species</u>, otherwise, this could severely endanger animal health and welfare.</p> <p>Proposed change: Scientific advice will be provided on the</p>	

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		implementation of the new legislation pertaining to restrictions on the use of certain antibiotic classes under the cascade.	
Line 83		<p>Comment: Aim 6 – would be good to add a reference to the impact on animal health and welfare</p> <p>Proposed change: refer to impact on animal health and welfare</p>	
Line 97		<p>Comment: 'Aim 1. Provide opinions to support the authorisation of effective antimicrobial VMPs with measures ensuring safe and sustainable use'. What is exactly meant by "sustainable use"?</p> <p>Proposed change: please explain sustainable use.</p>	
Line 126		<p>Comment: What is meant with 'alternative antibiotics'? Does it refer to the CVMP paper on alternatives to antibiotics or the O'Neill report mentioned inline 218? As commented in our response to that paper, most products which are considered as alternatives to antibiotics are not real alternatives. Most stimulate the immune response or have a preventive effect, while only a few of them have a direct curative effect.</p> <p>Proposed change (if any): please define 'alternative antibiotics' and include some examples</p>	

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Line 140		<p>Comments: What is meant with 'non-antibiotic antimicrobials'? Does it mean antivirals or anti-fungals? We should be careful with promoting the use of new substances until we are sure that they are not contributing to the problem, e.g. leading also to resistance, and that their use is science- and evidence-based without unforeseen negative consequences.</p> <p>Proposed change (if any): please explain what is meant with 'non-antibiotic antimicrobials' and include some examples</p>	
Line 158		<p>Comment: In aim 3, the 3 yearly JIACRA report continuation is mentioned. The JIACRA report is highly welcome. However, it is recognised that this report makes use of data collected by different surveillance/monitoring systems with different aims and primary purposes in each sector. The integrated analysis of such data is inherently hindered by this bias. The availability of more detailed and comprehensive data would increase the scope of the analyses that can be performed and improve the robustness of the outputs. We suggest that CVMP also adds an action together with ECDC and EFSA to work towards a more coherent methodology of collecting data for the JIACRA report which will facilitate the interpretation and analysis of the results.</p> <p>Proposed change: add an action for CVMP together with</p>	

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		ECDC and EFSA to work towards a more coherent methodology of collecting and interpreting data for the JIACRA report.	
Line 158, 253		<p>Comment: In aim 3 and 5, please insert a reference on how the UPD can facilitate the availability and support veterinarians in responsible prescribing</p> <p>Proposed change (if any): please add a reference to the role of UPD</p>	
Line 183 and Line 210		<p>Comment: ' CVMP will also investigate the barriers preventing access to, and use of, certain Category D antibiotics that could reduce the use of critically important antimicrobials in animals.' This is very welcome and urgently needed. However, should be accessible to all lower category antibiotics. Sometimes only a Cat B is available, then Cat C would also be beneficial</p> <p>Proposed change (if any): change to 'CVMP will also investigate the barriers preventing access to, and use of, certain Category C or D antibiotics that could reduce the use of critically important antimicrobials in animals'.</p>	
Line 197		<p>Comment: It is important, that actions should be aimed at keeping the benefit-risk relation positive. Unnecessary re-assessment with additional studies should be avoided as they</p>	

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		<p>will impose a high burden and may put products at risk of being taken out of the market. Any decision on re-assessment with additional studies should be science- and evidence-based and avoid the risk to lead to a reduced availability of different classes of antimicrobials for the veterinary treatment.</p> <p>Proposed change (if any):</p>	
Line 243		<p>Comment: While it is not further detailed what ATA will be, it would be good to emphasize that measures preventing disease and thus reducing the need for treatment are important. In saying this, vaccines definitely play a role to prevent diseases. They are well regulated, contrary to many other ATAs. Re vaccines, it is also important to allow and facilitate the use of products available in other member states, in case they are not available for use in the country of origin.</p> <p>Another aspect around ATAs is that many products are on the market as feed additives or just as products without authorisation to add to the feed. It would be good to have a clear regulation for the different types of products and more investment in research, such as to show that these products are really effective and pose no harm.</p>	

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		Proposed change (if any): Add a sentence on the use of vaccines and one on regulation of ATAs (feed additive, VMPs without authorisation)	
Line 253		<p>Comment: Aim 5 – responsible use. One barrier to promoting more responsible and prudent use is the narrow phrasing in the Regulation that VMPs have to be used according to the MA/SPC. In some cases, we know that the dose can be lowered or the duration can be shortened, but this is currently not allowed to do under the Regulation. Further to this, in order to minimise sales and spillage, veterinarians should be allowed to break up the outer package (while ensuring the inner package remains undamaged and given all extra information to the client). Some veterinary antimicrobials are only available in too big packages, which leads to a large amount of left-overs that the owner has to throw or is tempted to self-medicate their animal when having a problem in the future.</p> <p>Proposed change: investigate to allow veterinarians the possibility to divert from the SOP for well justified reasons, such as to allow to break up outer packages to avoid spillage and self-medication.</p>	

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Line 287		<p>Comment `The overall public health goal of the action plan is to ensure, for as long as possible, continuity of treatment and prevention of infectious disease with effective safe medicines that are quality-assured, used in a responsible way and accessible to all who need them.` This is a bit confusing. Antibiotics should be used for treatment. Other products like vaccines or ATA can be used for prevention. Moreover, prevention against infections, embraces animal husbandry, effective biosecurity and better feeding and housing conditions.</p>	

Please add more rows if needed.